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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,156	11/14/2003	Mitchell I. Kirschner	718689	2373
7590	03/18/2005		EXAMINER	
Richard H. Shear Blackwell Sanders Peper Martin, LLP 24th Floor 720 Olive Street St. Louis, MO 63101			CHOI, FRANK I	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 03/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,156	KIRSCHNER ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-40, 43-60, 63-80 and 83-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-40, 43-60, 63-80 and 83-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63,71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant does not indicate where in the present Specification which discloses that the suspension minimizes stomach upset. Applicant's citation to the parent case is insufficient as there is no mention of a suspension in the section cited.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-40,43-60,63-8082 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hermelin et al. (US Pat. 6,258,846) or Abbruzzese et al. (US Pat. 6,077,828), each in view of the acknowledged prior art, Opheim (US Pat. 6,346,231), Manufacturing Chemist & Aerosol News, Cuca (US Pat. 4,656,028) and Remington's.

Hermelin et al. teach nutritional supplements for women comprising soft gelatin capsules containing linoleic acid, linolenic acid and docosahexaenoic acid, derived from plant or fish oils,

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other vitamins, such as vitamin E, minerals, folic acid, including folic acid in a controlled release form (see entire document). It is taught that calcium is preferably present in the composition and embodiments art taught containing calcium (Column 12, lines 16-25, Column 16, lines 35-68, column 17, lines 1-25, 60-68, Column 18, lines 1-16)

Abbruzzese et al. teach a nutrition supplement containing mixture of omega-6 and omega 3 fatty acids, having 12-24 carbons, such as linoleic, linolenic, eicosapentaenoic, docospentaenoic and docosahexaenoic acid, vitamin D, Vitamin E, folic acid and calcium, which can be administered in capsules (See entire document, especially, Column 3, lines 10-43, column 4, lines 36-55, Column 5, lines 25-40, Column 7, lines 44-68, columns 8-20).

Applicant acknowledges that in women in pregnancy have digestive disturbances, including heartburn, gastroesophageal reflux, dyspepsia, regurgitation and increased sensitivity to unpleasant odors and/or tastes (Pg. 1, lines 14-25).

Opheim teaches the use of soft gelatin capsules to improve the palatability of fish oils, such as EPA and DHA (See entire document).

Manufacturing Chemist & Aerosol News teaches that soft gelatin capsules containing omega-3-fatty acids are easy to swallow (Abstract).

Cuca teaches the encapsulation of calcium carbonate in soft gelatin capsules which is used as an antacid (Columns 1,2).

Remington's discloses that suspensions may be expected demonstrate improved bioavailability because the suspension already contains discrete drug particles, whereas, tablet dosage forms must invariably undergo disintegration in order to maximize the necessary dissolution process (pg. 328). Further, it is disclosed that linoleic acid increased bioavailability of a drug due to its effect on gastrointestinal motility (Pg. 328).

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The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a formulation containing linolenic and linoleic acid and other omega fatty acids and calcium compounds. However, the prior art amply suggests the same as the prior art discloses nutritional composition which contain linolenic, linoleic and other omega fatty acids and vitamins and minerals, including vitamins E and D, folic acid and calcium, overcoming the unpleasant taste of omega-3-fatty acids by using soft gelatin capsules, that soft gelatin capsules containing omega-3-fatty acids are easy to swallow, that calcium compounds are suitable for use in nutritional formulations and that calcium carbonate antacids can be formulated in soft gelatin capsules. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that a soft gelatin capsule containing linolenic acid, linoleic acid and other omega-3-fatty acids and vitamins and minerals, including vitamins E and D, folic acid and calcium would well tolerated by the patient.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

As a preliminary matter, Applicant has cited to several references, which are not part of the record, which purport to support Applicant's arguments but Applicant does not appear to have provided copies of the same (See Remarks (9/10/2004), pgs. 17, 18). Without said evidentiary documents, Applicant's arguments are unsupported and amount to nothing more the arguments of counsel. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 43 USPQ2d 1362 (Fed. Cir.

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1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.").

Applicant maintains that it is entitled to the May 27, 1999 filing date of the 09/320559 Application. However, this application is only an indirect continuation-in-part of the '559 Application. As such, any claims which contain subject matter which was not enabled or disclosed in the '559 application are not entitled to the May 27, 1999 filing date. Applicant admits that essential fatty acids, essential fatty acid precursors, essential fatty acid derivatives and omega-3 and omega-6 fatty acids, precursors and derivatives were not explicitly disclosed in the '559 parent application. (Remarks (9/10/2004), pg. 16,17). Applicant then argues that oils disclosed in the '559 application were known to contain the above. However, it is equally true that the oils contain other components. Applicant provides no basis why one of ordinary skill in the art would at the time the '559 application was filed pick and choose the above components versus the other components of the oils.

In any case, even assuming that Applicant's broad disclosure in the '559 application was sufficient to enable one of ordinary skill in the art to choose the above components from oils, 35 USC Section 112, 1st paragraphs requires that the disclosure provide sufficient written description and enablement of the claimed invention. Applicant has admitted that there is no explicit disclosure of the above components. As such, the rejection herein is applicable to the claims herein. See *Studiengesellschaft Kohle v. Shell Oil*, 42 USPQ2d 1674, 1677 (CAFC 1997) (35 USC Section 120 requires an applicant to meet the disclosure requirement of Section 112, paragraph 1 in a single parent application in order to obtain an earlier filing date for individual claims); *In re Ruschig*, 154 USPQ 118,123 (CCPA 1967) (even assuming that the Specification was enabling for claimed compound this was insufficient for purposes of satisfying Section 112, paragraph 1 in that the Specification lacked written description of said compound).

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Applicant argues that high levels of amino acids are contraindicated as dietary supplements for the pregnant and nursing women targeted in the application. However, none of the claims exclude high levels of amino acids. In any case, "[w]hether persons of ordinary skill in the art disagree as to the safety of a product or techniques does not determine the issue of obviousness. The issue regarding obviousness is whether the differences embodied in a combination product and the result so produced would have been non-obvious to a person of ordinary skill in the art, not whether there was a controversy over whether such was safe."

Nickola v. Peterson, 193 USPQ 443, 447 (DC EMich) (citing to *In Re Jansen*, 187 USPQ 743 (Cust. & Pat. App., 1975)).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant provides no evidence that one of ordinary skill in the art would not be able to substitute plant and marine fish oils for PEG. The primary references of prior art as indicated above disclose the combination of plant and/or marine oils with calcium. Applicant does not cite to any disclosure in Cuca which states a preference of calcium suspension in PEG over the vegetable oil suspensions disclosed in Stanley. In fact Cuca specifically discloses the use of vegetable oil as a carrier (Cuca, Column 3, line 15). The mere fact that Manufacturing Chemist

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and Aerosol news citation does not disclose other components is insufficient to overcome the rejection. As indicated above, there is no requirement that said news citation recite each and every component of the claimed invention.

With respect to claims 63, 71, Examiner is at a loss as to how the present claims and prior art of record could have been discussed with Applicant in a telephone interview of April 8, 2003 when the present Application was filed on November 14, 2003. If Applicant is referring to an interview which may have occurred in a parent case, that was a parent case and would appear to have no bearing on the present application. Applicant has made no showing that the claim language and prior art which may have been discussed on April 8, 2003 is identical to the claim language and prior art applied in the present application. In any case, there is no link between the calcium and the functional language. The functional language appears to relate to the suspension not calcium per se.

In any case, the prior art, as indicated above, discloses and/or suggests a suspension containing nutrients, and a calcium compound which will minimize stomach upset, linoleic acid and one of ordinary skill in the art would expect that the suspension would increase bioavailability versus that of a tablet formulation as the nutrients are contained in the suspension, once released from the gel capsule, would not have to be first disintegrated from a tablet matrix before being available for absorption or by the effects of the linoleic acid on gastrointestinal motility.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

March 15, 2005



JOHN PAK
PRIMARY EXAMINER
GROUP 1600